REMARKS

Claims 22-38 and 56, as amended, appear in this application for the Examiner's review and consideration. Claim 22 has been amended to more clearly define the invention. Claims 23, 50 and 58 have been amended to be consistent with amended claim 22. Claim 37 has been amended to recite a preferred feature of the invention. As no new matter is introduced, entry of the amendments at this time is respectfully requested. It is understood that process and system claims 40-48, 50, 53-55 and 57-79 have been withdrawn from consideration but will be rejoined when method claim 22, on which they directly or indirectly depend, is allowed.

Claims 22-25 and 37 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. patent No. 5,958,447 to Haralambopoulos et al. (referred to hereafter as "Haralambopoulos"). Haralambopoulos teaches powdered patches wherein an active substance in a powder form becomes incorporated or embedded in the adhesive matrix of a transdermal patch by application of heat and/or pressure. Thus, according to Haralambopoulos, the active substance in a powder form is embedded into the adhesive matrix of the transdermal patch. In contrast, the present invention discloses that the pharmaceutical composition comprising the active agent is localized on the surface of the liner of the printed patch on which the pharmaceutical composition is applied. This is disclosed in paragraphs [0109] and [0195] and in FIG. 8 of the current application. Moreover, no pressure is involved in making the printed patches of the present invention as such patches are made by simple drying, as disclosed in paragraphs [0109] and [0152] of the current application.

Haralambopoulos further teaches printed patches that are formed by printing a bioactive liquid on an adhesive matrix using a printing roller. After printing, a release liner is brought into contact with the adhesive matrix so that the bioactive liquid diffuses into the adhesive matrix. Thus, the printed patches disclosed by Haralambopoulos include a bioactive liquid which diffuses into the adhesive matrix. In contrast, the printed patch of the present invention comprises a dried pharmaceutical composition which comprises an active agent. The dried pharmaceutical composition according to the present invention contains low residual moisture, which residual moisture is below 20%, preferably below 10%, more preferably below 5%, and most preferably below 3% of the final composition's weight, as disclosed in paragraph [0086] of the current application. Therefore, claims 22-25 and 37 are not anticipated.

Claims 22-26, 28-29, 37 and 56 were rejected under 102(b) as being anticipated by U.S. patent No. 5,611,806 to Jang et al. (referred to hereafter as "Jang"). The Examiner stated that Jang teaches Korean patent publication 92-2264 which discloses a patch type device for transdermally delivering insulin to patients (col. 1 line 48). The Examiner asserted that the patch type device disclosed by Korean patent publication 92-2264 comprises an insulin solvent reservoir constituting a water swellable, high molecular, insulin carrying layer on which insulin is dispersed in a powder form, a needle support adapted to expand as the insulin solvent is discharged from the reservoir, and an electrode attached to the ceiling of the reservoir for supplying the reservoir and the bodily skin with electricity (col. 1 lines 50-60). However, it should be noted that while the patch type device disclosed by Korean patent publication 92-2264 comprises insulin dispersed in a powder form, it further comprises an insulin solvent reservoir which is discharged from the reservoir. In contrast, the printed patch of the present invention comprises a dried pharmaceutical composition which contains low residual moisture, as disclosed in paragraph [0086] of the current application. Therefore, claims 22-26, 28-29, 37 and 56 are not anticipated by Jang.

Claim 38 was rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos. As discussed above, the patches disclosed by Haralambopoulos are substantially different from the printed patch of the present invention. Moreover, the printed patch recited in claim 38 wherein the pharmaceutical composition further comprises at least one component selected from an anti-oxidant, a buffering agent and a preservative is neither taught, nor suggested by Haralambopoulos. Therefore, claim 38 is not obvious over Haralambopoulos.

Claims 26, 28-29 and 32-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of U.S. patent No. 6,274,166 to Sintov et al. (referred to hereafter as "Sintov"). As explained above, Haralambopoulos teaches transdermal patches for powdered, liquid or semi-liquid pharmaceutical or cosmetic substances, which substances are suitable for topical administration, but does not teach the presently claimed patch structure or the use of insulin as an active agent. Sintov teaches proteins that can be incorporated into adhesive patches and all the examples disclosed by Sintov relate to topical application of insulin in solution on the skin of animals. Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising large molecules

such as insulin into a printed patch. Furthermore, even if Sintov is combined with Haralambopoulos, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, Sintov does not remedy the deficiencies of Haralambopoulos so that claims 26, 28-29 and 32-33 are patentable over this combination of references.

Claims 27, 29 and 32-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Haralambopoulos in view of U.S. patent No. 6,274,582 to Marin et al. (referred to hereafter as "Marin"). As explained above, Haralambopoulos teaches transdermal patches for powdered, liquid or semi-liquid pharmaceutical or cosmetic substances, which substances are suitable for topical administration, but does not teach the presently claimed patch structure or the use of human growth hormone (hGH) as an active agent. Marin teaches the use of hGH in combination with a cortisol synthesis inhibitor for preventing or treating conditions related to Metabolic Syndrome. Though Marin teaches that the active agents or compositions may be formulated as transdermal patches (col. 5 lines 37-41) and the administration may be transdermally (col. 5 lines 48-49), hGH was administered by subcutaneous or intramuscular injection in solution in all the examples of Marin (col. 3 lines 56-57 and col. 6 lines 9-13). Thus, it would not be obvious to one of ordinary skill in the art at the time the invention was made to formulate a dried pharmaceutical composition comprising large molecules such as hGH and saccharose into a printed patch for transdermal delivery. Furthermore, even if Marin is combined with Haralambopoulos, one of ordinary skill in the art would not obtain the presently claimed invention. Therefore, Marin does not remedy the deficiencies of Haralambopoulos so that claims 27, 29 and 32-34 are patentable over this combination of references.

Claims 22-26, 29-36 and 38 were provisionally rejected for nonstatutory obviousness-type double patenting over the claims of copending application 11/327,016. It is noted that the provision has not occurred in that application so that this rejection should be withdrawn at this time, since it is holding up the allowance of the present application. Applicant agree to file a terminal disclaimer in this or the copending application, whichever is found to be allowable at a later time than the other, to avoid any possible obviousness type double patenting issues.

In view of the above, it is believed that the entire application is in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a

telephonic or personal interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the claims.

Respectfully submitted,

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Allan A. Fanucci (Reg. No. 30,256)

WINSTON & STRAWN LLP
Customer Number 28765
(212) 294-3311